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| 10/553,999 | 12/30/2005 | Roland Barten | GAS-012 | 1346 |
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| EXAMINER | | | | |
| GERIDO, DWAN A | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/553,999

Applicant(s)

BARTEN ET AL.

Examiner

Dwan A. Gerido, Ph.D.

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 28-32 is/are rejected.
- 7) ☒ Claim(s) 27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/22)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the means for attaching the device in a receptacle, recited in claim 31 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claim 10, recites a device comprising two detachable chamber, whereas claim 1, from which claim 10 depends does not recite two detachable chambers. It is unclear if the two detachable chambers represent a typographical error, or if applicant intends to recite a device comprising two detachable chambers.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(c), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-13, 16-20, 23-26, and 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler (US 4,585,623) in view of Mercereau (US 5,377,689).

9. Regarding claim 1, Chandler teaches a device for chemical and immunochemical assays comprising a first chamber (figure 7 #17), second chamber (figure 7 #15), wherein the first and second chambers have means for reversibly changing their volume (figure 7 #25), and are connected by a first channel (figure 7 #20, column 2 lines 66-68). Chandler also teaches a connector (figure 7 #12) connected to the channel and having a means of flow regulation (figure 7 #30). Additionally, Chandler teaches the device comprising a detachable chamber (figure 1 #40) connected to the first channel (figure 7 #'s 12 and 20). Chandler does not teach a sealed detachable chamber.

Mercereau teaches a sampling syringe wherein the syringe comprises a seal (column 5 line 67 - column 6 line 2). Mercereau teaches that it is advantageous to utilize a seal as a means of blocking fluid flow through the plunger and for preventing atmospheric contaminants from entering the sample (column 1 lines 50-57). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Chandler in view of Mercereau to include a seal on a syringe in order to prevent atmospheric contaminants from contacting the sample as taught by Mercereau.

10. Regarding claim 2, Chandler recites the device being utilized for diagnostic medical testing (pregnancy test) therefore; it would be designed as a single use device.
11. Regarding claim 3, Chandler teaches the first and second chambers without a means of flow regulation between the two chambers (figure 7 #'s 15 and 17).
12. Regarding claim 4, Chandler teaches a second chamber comprising a means for reversibly changing volume (column 3 lines 4-7).
13. Regarding claim 5, Chandler teaches a first connector connected to the first chamber and extending opposite the first means for changing volume (figure 7 #20).
14. Regarding claim 6, Chandler teaches a second chamber connected to, and extending from an end of the second chamber opposite the means for changing volume (figure 7 narrowed extension from channel 15).
15. Regarding claim 7, Chandler teaches a second channel extending from the second chamber (figure 2, channel between #'s 15 and 12).
16. Regarding claim 8, Chandler teaches the detachable chamber having a reversibly changeable volume and comprising a means for reversibly changing the volume (figure 1 #'s 40, 43, and 44). Chandler also teaches the detachable chamber connected to the first and second chambers through a channel (figure 7 #20).
17. Regarding claim 9, Chandler teaches valves between the first and second chambers, and a detachable chamber (figure 7 #30).
18. Regarding claim 10, Chandler teaches a waste chamber with a flexible membrane to accommodate an increased volume between two chambers (column 3 lines 18-29, figures 5-7, #'s 35 and 36). Chandler teaches that it is advantageous to utilize a waste chamber with a

flexible membrane to remove the need of a vent for the waste reservoir. Chandler does not explicitly teach the volume of the waste chamber being larger than the total compressible volume of the system; however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Chandler wherein the waste chamber has a volume larger than the total volume of the system in order to accommodate the volume of fluid waste and to remove the need for a vent within the waste reservoir as taught by Chandler.

19. Regarding claim 11, Chandler teaches the detachable chamber being tapered opposite the means for reversibly changing the volume (figure 1 #46). The limitation of the tapered end being located at the first channel is sufficiently broad so as to be read on the device of Chandler which teaches the tapered end of the detachable chamber connected to the channel through an additional chamber (figure 1 #12).

20. For claims 12, 13, and 16, Chandler teaches the means for changing volume in the chambers as a piston (column 4 lines 4-7, figure 7 #50) wherein the pistons and chambers have identical shapes (circular) and not connected to a piston rod.

21. Regarding claim 17, Chandler teaches the chambers having an essentially round cross-section (figure 2 #'s 12-14, 16, 18).

22. Regarding claim 18, Chandler teaches the detachable chamber connectible to the first channel (figures 1 and 7).

23. Regarding claim 19, Chandler teaches the axes of the chambers being parallel (figures 1 and 7).

24. Regarding claim 20, Chandler teaches a chamber having a solution that dissolves the substrate which is being read on the claimed solubilizing solution (column 3 lines 60-63).

25. Regarding claim 23, Chandler teaches a wash solution, but does not teach the wash solution in the first and second chambers. It is advantageous to provide a wash solution in the first chamber of Chandler to provide a means of cleaning residual substrate residue from the first chamber. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Chandler in view of Mercereau wherein a wash solution is provided in the first chamber in order to clean residual substrate from the first chamber.

26. Regarding claim 24, Chandler teaches an elution solution, but does not teach the elution buffer in the first or second chamber. It is advantageous to provide an elution solution in the first or second chamber as a means of eluting a high concentration of reaction products from the chambers. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Chandler in view of Mercereau to wherein an elution solution is provided in the first or second chambers in order to extract a high concentration of reaction products from the chamber.

27. Regarding claim 25, Chandler teaches the connector (figure 7 #12) comprising a valve for flow regulation (figure 7 #30).

28. Regarding claim 26, the detachable chamber of Chandler (figure 1 #40) would be fluid tight with connector (figure 7 #12) is closed by the valve (figure 7 #30) at the end of connector 12.

29. Regarding claim 28, Chandler teaches the device provided with an enclosure made of synthetic material (column 2 lines 25-27, column 5 lines 29-37).

30. Regarding claim 29, Chandler teaches the channels and connectors in a base plate (figure 2).

31. Regarding claim 30, Chandler teaches the device being open at the edge of an enclosure (figure 1).
32. Regarding claim 31, Chandler teaches the device having a preprogrammed operating and analyzing device and a rib (figure 1 #62) for attaching the device in a receptacle.
33. Regarding claim 32, Chandler does not explicitly teach the components in a kit; however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify to assemble the components within a kit to attain the commercial advantage of providing the components of the device in a single package.
34. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler (US 4,585,623) in view of Mercereau (US 5,377,689) as applied to claim 1 above, and further in view of Schnipelsky et al., (US 5,229,297).
35. Regarding claims 21 and 22, Chandler in view of Mercereau do not teach magnetic particles within the chambers and/or channels.

Schnipelsky et al., teach a containment cuvette wherein magnetic particles are utilized for binding reaction products (column 17 lines 4-17). Schnipelsky et al., do not teach a specific diameter range for the magnetic beads; however, magnetic beads with small diameters are well known in the art, and applicant's ranges are sufficiently broad that one of ordinary skill would have found the claimed diameter ranges obvious. Schnipelsky et al., teach that it is advantageous to utilize magnetic beads as a means of separating the desired reaction products. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Chandler in view of Mercereau, in further view of Schnipelsky et al., to utilize magnetic

beads in order to efficiently separate reaction products from undesired reagents as taught by Schnipelsky et al.

Allowable Subject Matter

36. Claim 27 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

37. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record does not teach or suggest a device for contamination free preparation of analyte comprising a magnet located at the end of the first, second, and at least one detachable chamber.

Response to Arguments

38. Applicant's arguments with respect to claims 1-32 have been considered but are moot in view of the new ground(s) of rejection.

39. Applicant has argued that reference to Chandler does not anticipate the instant claims, and has amended independent claim 1 to recite a detachable chamber that is selectively connectable to the first channel. The examiner asserts that reference to Chandler teaches a detachable chamber (figure 1 #40) that is selectively connectable to a channel (figure 7 #20) through a connector (figures 1 and 7 #12). Chandler also teaches a device comprising first and second chambers (figure 7 #'s 17, 15) connected by a channel (figure 7 #20) and having a means for reversibly changing the volume of each chamber (figure 7 #25). The language of claim 1 regarding the structure of the device is sufficiently broad so as to be read on the device taught by Chandler. Reference to Chandler has been modified with the teachings of Mercereau which

teaches a syringe that is sealed to prevent contamination and unwarranted fluid flow. Thus it is the examiners position that the combination of Chandler in view of Mercereau teaches the limitations of independent claim 1.

Regarding applicant's arguments for claim 3, chambers 17 and 15 of Chandler (see figure 7) are being read as the first and second chamber. As shown in figure 7 of reference to Chandler, chambers 17 and 15 do not comprise a means of flow regulation at the end of the chambers, and are connected by a channel denoted as #20 in figure 7. Given this interpretation, it is the examiner's position that the device as taught by Chandler meets the limitations of claim 3.

Regarding applicant's arguments for claim 10, the examiner respectfully disagrees that it is speculation that it would have been obvious to provide a waste chamber having a volume larger than the compressible volume of the system. It is the examiner's position that one of ordinary skill would have found it obvious to form the waste chamber capable of at least accommodating the volume of the system so as to effectively remove waste from the device and prevent interference with reagents. Additionally, having a waste chamber volume larger than that of the system allows for variety in the volume of reagents that can be added, and for scaling up reactions as a larger volume of reagents would create a larger volume of waste products.

Regarding applicant's arguments for claim 11, forming the chambers with a tapered portion does not alter the structure or function of the overall device, and therefore is read as a design choice that would have been obvious to one of ordinary skill in the art.

Regarding applicant's arguments for claims 14 and 15, the claims merely require a piston made of an elastic material which is taught in reference to Kimura. Thus it is the examiners

position that it is known in the art to form pistons from an elastic material as this feature is taught by Kimura.

Regarding applicant's arguments for claims 21 and 22, the examiner asserts that magnetic particles are very well known in the art, and that applicant's diameter ranges are sufficiently broad that one of ordinary skill would have found the claimed diameters obvious. As a rebuttal to applicant's call for a citation of magnetic beads with small diameters, the examiner would like to draw applicant's attention to US Patent 6,117,398 to Bienhaus et al., which teaches a similar device having magnetic particles with an average diameter of 2.8 μ m which is within the range of the claimed diameters.

Regarding applicant's arguments for claims 30, and 31, reference to Holtzman has been removed and claims 30 and 31 are rejected as unpatentable over Chandler in view of Mercereau as detailed above.

Conclusion

40. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwan A. Gerido, Ph.D. whose telephone number is (571)270-3714. The examiner can normally be reached on Monday - Friday, 9:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LYLE A ALEXANDER/
Primary Examiner, Art Unit 1797

DAG